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Ambient Water Quality Criteria Document Addendum for Phenol

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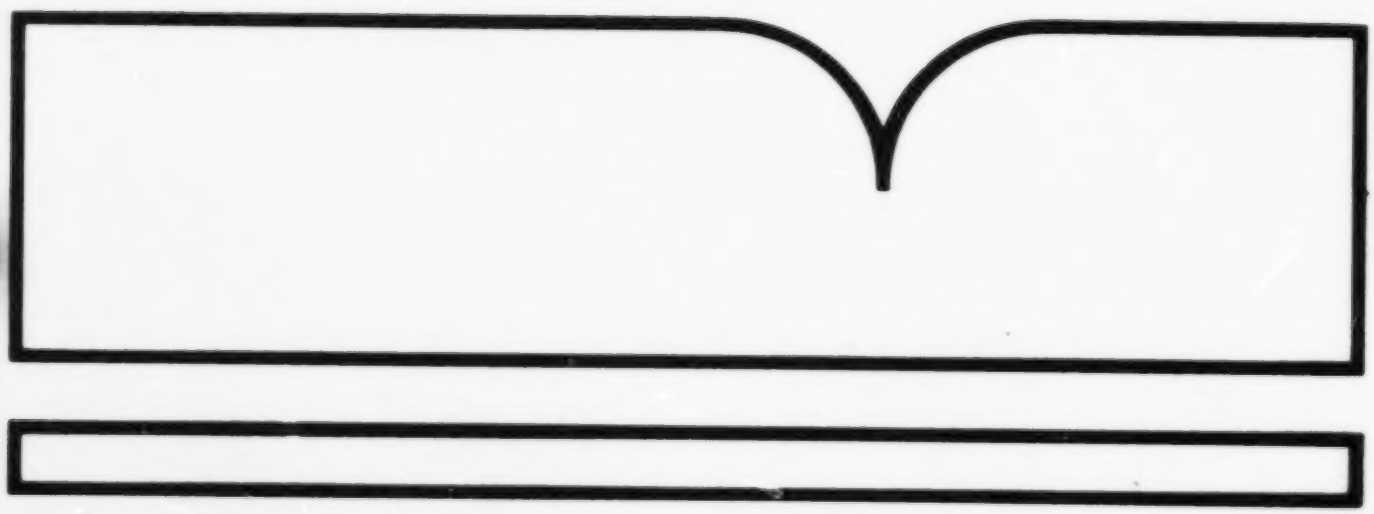

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ADDENDUM FOR PHENOL

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OFFICE OF WATER REGULATIONS
AND STANDARDS

Prepared by

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Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority Pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information form Agency files and Program Offices. This addendum is to update the existing Ambient Water Quality Criteria Document for Phenol.

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PREFACE

Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information from Agency files and Program Offices. The first draft of this addendum was prepared by Syracuse Research Corporation under contract no. 68-C8-0004.

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LIST OF ABBREVIATIONS

ADI	Acceptable daily intake
BCF	Bioconcentration factor
CRAVE	Carcinogen Risk Assessment Verification Endeavor
LOAEL	Lowest-observed-adverse-effect level
NOAEL	No-observed-adverse-effect level
NOEL	No-observed-effect level
PEL	Permissible exposure level
ppm	Parts per million
RfD	Reference dose
RQ	Reportable quantity
STEL	Short-term exposure level
TLV	Threshold limit value
TWA	Time-weighted average

INTRODUCTION

Under Section 304(a)(1) of the Clean Water Act of 1977 as amended in 1987, the U.S. EPA is required to publish criteria for water quality accurately reflecting the latest scientific knowledge regarding the effects on health and welfare that may occur from the presence of pollutants in any body of water, including groundwater. In accordance with the 1977 act, Ambient Water Quality Criteria Documents (AWQCDs) were developed in 1980 for 65 toxic pollutants or classes of pollutants listed under Section 307(a)(1).

These addenda are intended to serve as an update of the original AWQCDs. The addenda provide the Agency with the latest scientific assessments of potential health hazards associated with these pollutants and serve as guidelines for modifying the current (1980) AWQCDs.

The human health criteria in these addenda are based on Agency verified risk assessment values when available. These values consist of reference doses (RfD) for those chemicals believed to be systemic toxicants (i.e., do not induce cancer) and cancer risk factors for those thought likely to cause cancer in humans. The verification process consists of a review and consensus of risk assessment values provided by an Agency workgroup consisting of scientists from each of the major Agency offices. Assessments for noncarcinogens are verified by the RfD workgroup and those for carcinogens are verified by the Carcinogen Risk Assessment Verification Endeavor (CRAVE) workgroup. If such values are not available, the criteria are based on the most recent Agency health assessment. In the absence of any appropriate Agency value, RfD values or cancer risk factors are derived by current Agency methods if adequate new data are available, and criteria are recommended based on the proposed RfD or risk factor.

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is derived by dividing a NOAEL or LOAEL for subchronic or chronic exposure by standard uncertainty factor(s) times an additional uncertainty factor:

$$RfD = \frac{\text{NOAEL or LOAEL}}{UF(s) \times UF}$$

The standard uncertainty factors are applied to reflect the various types of data used to estimate RfDs. An uncertainty factor of 10 is used to account for variations in human sensitivity when extrapolating from valid human studies involving long-term exposure of average, healthy subjects. An additional 10-fold factor is used for each of the following: to extrapolate from long-term animal studies to the case of humans, to extrapolate from subchronic animal studies to chronic exposure, and to extrapolate from a LOAEL to a NOAEL. An additional uncertainty factor of >0-10 may be applied to reflect professional assessment of the uncertainties of the study and data base not explicitly addressed by the standard uncertainty factors (i.e., completeness of the overall data base). The default value for the additional uncertainty factor is 1.

In assessing the carcinogenic potential of a chemical, the U.S. EPA classifies the chemical into one of the following groups according to the degree of evidence in epidemiological studies and animal studies: Group A - Human Carcinogen; Group B - Probable Human Carcinogen [limited evidence in humans with or without sufficient evidence in animals (Group B1) or inadequate evidence in humans with sufficient evidence in animals (Group B2)]; Group C - Possible Human Carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); Group D - Not Classifiable as to

Human Carcinogenicity (inadequate or no evidence); Group E - Evidence of Noncarcinogenicity for Humans. Quantitative carcinogenic risk assessments are performed for chemicals in Groups A and B, and on a case-by-case basis for chemicals in Group C. Upper-bound cancer unit risks (slope values) are estimated through the use of mathematical extrapolation models. Most commonly for animal data, the linearized multistage model with a 95% upper confidence limit is used to provide a low-dose estimate of cancer risk. The cancer risk is characterized as an upper-limit estimate (i.e., the true risk to humans, while not identifiable, is not likely to exceed the upper-limit estimate and in fact may be lower). Alternative risk models to the multistage model, such as the one-hit, Weibull, Logit or Probit model, are available and may be used when the evidence indicates that they may be more appropriate. In the absence of such evidence, the Agency recommends the linearized multistage model to provide consistency of approach and an upper-bound on the potential carcinogenic risk. In the case where human data are used for quantitative risk assessment, an upper-bound estimate rather than a 95% upper-bound estimate is used when low-dose linearity is assumed.

In the development of this Addendum to the AWQCD on phenol, recent Agency assessments have been consulted. A computerized literature search was conducted to cover studies published more recently than the latest Agency assessment (i.e., published in 1986 to 1988). New key studies have been evaluated.

REVIEW OF NEW DATA

Toxicologic/Carcinogenic Effects

In a subchronic toxicity study conducted by NCI (1980), B6C3F1 mice and F344 rats (10/sex/group) were given phenol in the drinking water for 90 days at concentrations of 0, 100, 300, 1000, 3000 and 10,000 ppm. Parameters studied were body weight, appearance, behavior, food and water consumption and tissue histology. No effects were noted in either species at exposure levels $\leq$3000 ppm ($\leq$780 and 1700 mg/kg/day for rats and mice, respectively). At 10,000 ppm, there was a decrease in water intake and weight gain, but no histopathologic changes were noted.

In a chronic bioassay study, groups of rats and mice (50/sex) were also administered doses of 0, 2500 or 5000 ppm phenol in the drinking water for 103 weeks (NCI, 1980). The low dose (153 and 313 mg/kg/day for rats and mice, respectively) induced a decrease in weight gain and water intake. Furthermore, male and female rats treated with the high dose of phenol (344 mg/kg/day) showed chronic kidney inflammation. Survival was not affected in either species.

The carcinogenicity of phenol administered in the drinking water of rats and mice was also studied (NCI, 1980). Male rats given 2500 ppm phenol had statistically significant incidences of pheochromocytomas, leukemias or lymphomas when compared with controls; however, the incidences of these neoplasms were not significant when comparing the high-dose (5000 ppm) males to controls. Low-dose male rats had an increase in C-cell carcinoma of the thyroid and a slight increase in the incidence of interstitial cell tumors of the testis. No increases in tumor incidences were noted, however, in treated female rats and in treated male and female mice when compared with the appropriate controls. NCI (1980) concluded that the results of the study were negative.

In a recent reevaluation of the available literature, the U.S. EPA (1989) derived an oral RfD of 0.6 mg/kg/day based on the results from a study conducted by the NTP (1983). Phenol was administered by gavage at doses of 0, 30, 60 or 120 mg/kg/day in distilled water to pregnant CD rats (20-22/group) on gestational days 6 to 15. Females were weighed daily during treatment and observed for clinical signs of toxicity, and detailed teratological evaluations were conducted at sacrifice. Results of this study did not show any dose-related signs of maternal toxicity or any clinical symptoms of treatment-related toxicity. The number of implantation sites per litter was approximately the same in all groups, as was the number of live fetuses per litter. However, since implantations in this strain take place prior to gestational day 6 (prior to dosing), no relationships between treatment and number of implantation sites can be established. The most important finding, however, was a highly significant reduction in fetal body weights in the high-dose group. The highest fetal NOAEL in this study was 60 mg/kg/day.

An unpublished study by Dow Chemical Co. (1945) reports that doses of phenol were administered by gavage to groups of 10 rats at doses of 0, 50 or 100 mg/kg, 5 days/week (adjusted to 0, 35.7 or 71.4 mg/kg/day on a 7-day basis). After treatment was completed, the rats were sacrificed for histopathologic examination. Rats receiving the highest dose showed a reversible depression in body weight gain. The six survivors in the highest dose group had slight cloudy swelling of the liver; four of these survivors also had some kidney damage. In 2/6 survivors in the 50 mg/kg group, there was a slight indication of kidney damage. Deaths were not treatment-related.

The Dow Chemical Co. (1945) report is supported by an earlier study by Deichmann and Oesper (1940) in which rats were administered phenol in

drinking water for 12 months at concentrations of 0, 800, 1200, 1600, 2000 and 2400 mg/ℓ. No effects on water consumption or weight gain were seen with concentrations ≤1600 mg/ℓ (49 mg/kg/day). The only effect noted was decreased weight gain at 2000 and 2400 mg/ℓ.

In two recent studies conducted by Jones-Price et al. (1983a,b) the teratogenicity of phenol was tested in Sprague-Dawley rats and CD-1 mice. There was no evidence of teratogenic effects in rats or mice. However, in both rats and mice, there was fetotoxicity in the high-dose animals (125 mg/kg/day). These studies are discussed in detail in U.S. EPA (1987).

Information regarding the effects on humans from oral exposure is limited. Baker et al. (1978) reported that groundwater contaminated with phenol resulting from an accidental spill in rural Wisconsin resulted in ~1 month exposure of area residents to 10-240 mg/day. Symptoms reported included diarrhea, mouth sores and burning mouth. Symptoms were reported to have occurred over a 7-month period.

Bioconcentration Factor (BCF)

More recent aquatic BCF information is available; however, evaluation of this data is currently undergoing Agency review. The BCF value of 1.4 determined in U.S. EPA (1980) will be used until this review is completed.

QUANTIFICATION OF EFFECTS

The U.S. EPA (1980) recommended an ambient water quality criterion for phenol of 0.3 mg/ℓ, based on a study by Dietz and Traud (1978) regarding organoleptic properties of phenol. U.S. EPA (1980) also indicated that based on the more recent toxicologic studies in rats (Dow Chemical Co., 1976) an ADI of 0.1 mg/kg/day can be calculated. This value is derived by applying an uncertainty factor of 500 to the LOAEL of 50 mg/kg. An uncertainty factor of 500 was thought to adequately reflect the size of the data base concerning long-term studies. Thus, using a BCF of 1.4 for phenol and assuming a daily intake of 2 ℓ of water and a daily consumption of 6.5 g of fish and shellfish by a 70 kg individual, the criterion for consumption of water and fish and shellfish would be 3.5 mg/ℓ and for the consumption of fish and shellfish alone would be 769 mg/ℓ.

U.S. EPA (1989) re-examined the literature and verified an oral RfD of 0.6 mg/kg/day based on the study by the NTP (1983) (see previous section). U.S. EPA (1989) used the 60 mg/kg/day NOAEL and applied an uncertainty factor of 100 (10 for interspecies and 10 for the wide range of human sensitivity) to derive the RfD of 0.6 mg/kg/day. Using the verified oral RfD ambient water criteria for phenol can be derived assuming a daily consumption of 2 ℓ of water and 6.5 g of fish and shellfish with a BCF for phenol of 1.4 by a 70 kg person. The criteria for consumption of water and fish and shellfish is 20.9 mg/ℓ and for consumption of fish and shellfish alone is 4615 mg/ℓ.

Based on the available evidence, phenol has been classified as a Group D chemical - not classifiable as to human carcinogenicity (U.S. EPA, 1987).

EXISTING STANDARDS AND CRITERIA

The verified chronic oral RfD is 0.6 mg/kg/day (U.S. EPA, 1989).

An RQ of 1000 pounds is proposed for phenol based on the natural biodegradation and photolysis of phenol (U.S. EPA, 1989).

The ACGIH TLV-TWA is 5 ppm (~19 mg/m^3); the STEL has been deleted (ACGIH, 1987). The OSHA PEL is the same as the ACGIH TLV-TWA (OSHA, 1985).

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